

REMARKS1. Status of the Claims

Claims 3, 6-8, 12, and, 21-22 are pending in the present application. Claims 3, 6, and 12 are amended herein. Support for the present amendments can be found in the specification, e.g., at page 7, lines 21-32 and page 54, lines 8-28 and in the Figures, e.g., in Figure 4. The Examiner is respectfully requested to enter claims 3, 6, and 12 as amended herein.

2. REJECTION OF CLAIMS 3, 6-8, and 21-22 UNDER THE JUDICIALLY CREATED DOCTRINE OF OBVIOUSNESS-TYPE DOUBLE PATENTING OVER CLAIMS 1-5 AND 8-15 OF U.S. PATENT NO. 5,753,504

Applicants note that the record shows that the present rejection was withdrawn in the Advisory Action mailed December 29, 2003.

3. REJECTION OF CLAIMS 3,6-8, 12, AND 21-22 UNDER 35 U.S.C. 102(b)

In the Advisory Action mailed December 29, 2003 (hereinafter, the Advisory Action), the Examiner maintains the rejection of claims 3, 6-8, 12, and 21-22 as being allegedly anticipated under 35 U.S.C. § 102(b) by Leturcq et al (Journal of Cellular Biochemistry (1992) Supplement 16, Part C, Page 151, Abstract CB109). The present rejection is respectfully traversed for the reasons discussed below and the reasons discussed in the Response After Final Office Action mailed October 27, 2003; which discussion the Examiner is requested to make a part of the record.

A. Monoclonal antibodies 8C9 and 18G4

In the Advisory Action, the Examiner maintains the present rejection allegedly "because monoclonal antibodies 8C9 and 18G4 [are] taught by Leturcq et al...".

Referring to monoclonal antibody 8C9, Leturcq et al., states, "One (8C9) of the three [antibodies] recognizes denatured LBP only". However, Figure 4, of the present specification, demonstrates that monoclonal antibody 8C9 of the present invention also specifically binds native LBP, for example. Thus, Applicants disclose and claim that monoclonal antibody 8C9 of the present invention has a binding specificity to LBP and to denatured LBP as disclosed in Figure 4 of the drawings and as set forth in claim 3. Accordingly, Leturcq et al., is not an enabling disclosure of the monoclonal antibody set forth in claim 3 of the present invention because it does not teach every element of the claimed invention. Therefore, the present rejection should be withdrawn because anticipation can only be demonstrated when each and every element of the claim is present and enabled in the prior art reference and because the binding specificity of 8C9 to native LBP is not disclosed or enabled in Leturcq et al.

Referring to monoclonal antibody 18G4, Leturcq et al., does not disclose a binding specificity of 18G4 to denatured LBP. Claims 3, 6, and 12 each recite a limitation that the monoclonal antibody has a binding specificity of Mab 18G4 to denatured LBP. Therefore, the present rejection should be withdrawn because each and every claim element is not present and enabled by the cited reference.

B. Binding Specificities of the Claimed Antibodies

In the Advisory Action, the Examiner also maintains the present rejection allegedly because, "The limitation that the monoclonal antibody including a binding specificity to LBP, to denatured LBP, and to a complex containing LBP and LPS of Mab 4D7, Mab 5C5, Mab 6B6, Mab 8C9, Mab 18G4 or Mab 24B7 does not change the structure of the claimed antibody, rather it describes binding specificities which the prior art antibodies are capable of meeting".

As discussed above for Mab 8C9 and Mab 18G4, Leturcq et al. does not meet the limitations of the binding specificities recited in the claims. Furthermore, Leturcq et al., does not teach Mab 4D7, Mab 5C5, Mab 6B6, or Mab 24B7. Therefore, Leturcq et al. cannot anticipate the claimed invention in regard to the latter antibodies, because each and every element of the claims is not disclosed and enabled by Leturcq et al.

Still further, the Examiner's statement that the claimed binding specificities allegedly do not "change the structure of the claimed antibody" is misapplied in support of an anticipation rejection. It is long standing practice in the biological arts to claim antibodies in terms of immunospecificity or binding specificity (see, e.g., MPEP 8Ed. 2163(3)(a), August 2001). The present rejection should be withdrawn.

C. Claims 21 and 22

Referring to the rejection of claims 21 and 22 under 35 U.S.C. § 102(b), this was a new rejection in the Final Office Action mailed August 26, 2003. The Examiner failed to state a basis for the present

rejection in the Final Office Action. The Examiner also failed to state a basis for the present rejection in the Advisory Action mailed December 29, 2003. Furthermore, claims 21 and 22 are compositions and no element in Leturcq et al. was identified against claims 21 and 22 by the Examiner. Accordingly, the present rejection should be withdrawn because no *prima facie* basis for a rejection of claims 21 and 22 under 35 U.S.C. § 102(b) is provided on the record.

CONCLUSION

The Applicant respectfully requests that the Examiner enter the response herein, withdraw all claim rejections, and place the claims in condition for allowance.

The Examiner is requested to contact the representative for the Applicants, to discuss any questions or for clarification. If there are any further fees associated with this response, the Director is authorized to charge our Deposit Account No. 19-0962.

Respectfully submitted,

Jan. 27, 2004
Date

Michael J. McCarthy
Michael J. McCarthy, Reg. No. 46,910

THE SCRIPPS RESEARCH INSTITUTE
10666 North Torrey Pines Road
Mail Drop TPC-8
La Jolla, California 92037
(858) 784-2937